

Please amend the application filed on even date herewith prior to proceeding with its examination.

IN THE CLAIMS

1. (Currently Amended) Self-supporting films comprising:
 - a) a filmogenic substance consisting of a maltodextrin,
 - b) a plasticiser,
 - c) an active ingredient for food or pharmaceutical use,

5 ~~wherein characterised in that~~ said films are free ~~from~~ of hydrocolloids.
2. (Currently Amended) Self-supporting films as claimed in claim 1, ~~wherein characterised in that~~ the maltodextrin (a) has a dextrose content of less than~~[t]~~ 50 expressed in equivalents.
3. (Original) Self-supporting films as claimed in claim 2 wherein said 10 dextrose content is between 11 and 40.
4. (Currently Amended) Self-supporting films as claimed ~~in any one of~~ in claims 1–3, ~~wherein characterised in that~~ the plasticiser is ~~[chosen]~~ selected from the ~~[class]~~ group consisting of polyalcohols, citric acid esters, sebacic acid esters or their mixtures.
- 15 5. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1[–4], ~~wherein characterised in that~~ the plasticiser is ~~[chosen]~~ selected from the ~~[class]~~ group consisting of propylene glycol, glycerine, sorbitol, maltitol and their relative mixtures.
6. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ 20 claims 1–5, ~~wherein characterised in that~~ the active principle for food use is an active principle with a breath freshening action and/or indicated for oral hygiene or an active principle suitable for nutritional supplementation.
7. (Currently Amended) Self-supporting films as claimed in claim 6, ~~wherein characterised in that~~ said active principle for food use is ~~[chosen]~~ selected 25 from the group consisting of menthol and eugenol.

8. (Currently Amended) Self-supporting films as claimed in claim 6 wherein said active principle suitable for nutritional supplementation is [chosen] selected from the group consisting of mineral salts normally used for such purpose[,] and vitamins.

5 9. (Original) Self-supporting films as claimed in claim 8 wherein the vitamin is ascorbic acid.

10. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-5, wherein characterised in that said active principle for therapeutic use is [chosen] selected from the group consisting of active principles with essentially topical activity.

11. (Currently Amended) Self-supporting films as claimed in claim 10, wherein characterised in that said active principle is [chosen] selected from the [class] group consisting of antibacterial, antimycotic, antiviral agents and disinfectants of the oral cavity.

15 12. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-5 wherein the active principle for therapeutic use is [chosen] selected from the [class] group consisting of active principles with essentially systemic activity.

13. (Currently Amended) Self-supporting films as claimed in claim 12, wherein characterised in that said active principle with essentially systemic activity is [chosen] selected from the [class] group consisting of anti-inflammatory, analgesic, antipsychotic, hypnotic, anxiolytic, antihypertensive, myorelaxant, antimigraine, antiparkinsonian, antiemetic, antihistaminic, beta blocking and antiasthmatic agents.

20 25 14. (Currently Amended) Self-supporting films as claimed in either of claims 12 or 13, wherein characterised in that said principle is [chosen] selected from the [class] group consisting of: Piroxicam, Ketoprofen, Sodium diclofenac, Tramadol hydrochloride, Morphine, Nifedipine, Diazepam, Lorazepam, Alprazolam, Bromazepam, Triazolam, Lormetazepam, Zolpidem, Paracetamol, 30 Selegiline, Atenolol, Salbutamol, Sumatriptan, Clozapine, Cetirizine, Ondansetron, Fentanyl and their pharmaceutically acceptable salts.

15. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims ~~1-14~~ 14, ~~characterised by~~ containing maltodextrin at concentrations between 40 and 80% by weight, plasticiser in concentrations between 15 and 55% by weight and the active principle for food or pharmaceutical use in a quantity between 0.05% and 30% by weight on the total weight of said film.

16. (Currently Amended) Self-supporting films as claimed in ~~any one of~~ claims 1-15, ~~characterised by~~ containing other excipients [chosen] selected from the [class] group consisting of anticaking agents, sweeteners, flavourings, colouring agents, preservatives, acidity regulating systems and mixtures thereof.

17. (Currently Amended) Self-supporting films as claimed in claim 16, ~~wherein characterised in that~~ said antisticking agents are [chosen] selected from the [class] group consisting of microcrystalline cellulose, colloidal silica and talc.

18. (Currently Amended) Process for preparing self-supporting films claimed in ~~any one of~~ claims 1-17, comprising the following steps:

i) mixing the maltodextrin, plasticiser and active principle for food or therapeutic use ~~are mixed~~,

ii) extruding the mixture coming ~~derived~~ from the preceding step ~~is extruded in an extruder~~.

19. (Currently Amended) Process as claimed in claim 18, [characterised in that] wherein the extrusion step (ii) is preferably conducted at a temperature between 60 and 120°C.

20. (Currently Amended) Process as claimed in ~~either of~~ claims 18 and ~~19~~, ~~characterised by~~ being conducted in a single screw extruder.

21. (Currently Amended) Process for preparing self-supporting films claimed in ~~any one of~~ claims 1-17, ~~characterised by~~ comprising the following steps:

i) dispersing the maltodextrin, plasticiser and the active principle for therapeutic or food use ~~are dispersed~~ in a polar solvent at a temperature between 60 and 105°C,

ii) rolling the mixture obtained in the preceding step ~~is rolled onto a~~ silicone paper ~~and dried it and then dried~~,

iii) removing the silicone paper ~~is removed~~ from the film obtained in the preceding step.

22. (Currently Amended) The Pprocess as claimed in claim 21, wherein characterised in that the polar solvent used in step (i) is preferably [chosen] selected from the [class] group consisting of water, a water miscible solvent and relative mixtures thereof.

5 23. (Currently Amended) Process as claimed in claim 22, wherein characterised in that said solvent consists of water and or a water-ethanol mixture.

24. (Currently Amended) Process as claimed in claim 23, wherein characterised in that the temperature of steps (i) and (ii) is between 60 and 105°C.

25. (Currently Amended) Process for preparing self-supporting films 10 claimed in any one of claims 1-17, comprising the following steps:
i) mixing the maltodextrin, plasticiser and active ingredient for food or therapeutic use are mixed,
ii) granulating the mixture was granulated, and sieving the mixture ed and mixing ed it with an anti sticking agent,
15 iii) storing the granules were stored at least for 12 h,
iv) extruding the granules coming derived from the preceding step were extruded in an extruder for thereby obtaining the edible film.

26. (Currently Amended) Process as claimed in claim 25, wherein characterised in that the extrusion step (ii) is preferably conducted at a 20 temperature between 70 and 140°C.

27. (Cancelled)